SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 13 June 2017

doi: 10.2903/j.efsa.2017.4898

Safety assessment of the process 'Märkische Faser', based on NGR technology, used to recycle post-consumer PET into food contact materials

Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Vittorio Silano, Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Sirpa Kärenlampi, Wim Mennes, André Penninks, Andrew Smith, Maria de Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle, Holger Zorn, Corina-Aurelia Zugravu, Vincent Dudler, Nathalie Gontard, Eugenia Lampi, Cristina Nerin, Constantine Papaspyrides, Cristina Croera and Maria Rosaria Milana

Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the safety assessment of the recycling process Märkische Faser (EU register number RECYC0135), which is based on the Next Generation Group (NGR) technology. The input to this process is hot washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, containing no more than 5% PET from non-food consumer applications. In this technology, post-consumer washed and dried PET flakes are melted and degassed in an extruder under vacuum (step 2) and decontaminated during a melt-state polycondensation under high temperature and vacuum (step 3). In step 4, the melt material is homogenised, extruded under vacuum and subsequently pelletised. Having examined the results of the challenge test provided, the Panel concluded that the steps 2, 3 and 4, are the critical steps for the decontamination efficiency of the process. The operating parameters which control the performance of these steps are well defined and are the temperature and pressure in all steps and the exposed surface area of the melt and its residence time of step 3. It was demonstrated that the recycling process under evaluation is able to ensure that the level of migration of potential unknown contaminants into food is below a conservatively modelled migration of 0.1 μg/kg food. The Panel concluded that recycled PET obtained from the process Märkische Faser is not of safety concern when used up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature. Thermoforming trays are not intended to be used and should not be used in microwave and conventional ovens.

Keywords: NGR technology, Märkische Faser, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany

Question number: EFSA-Q-2016-00139

Correspondence: fip@efsa.europa.eu

Panel members: Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Sirpa Kärenlampi, Wim Mennes, Maria Rosaria Milana, André Penninks, Vittorio Silano, Andrew Smith, Maria de Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle, Holger Zorn and Corina-Aurelia Zugravu.

Competing interests: In line with EFSA's policy on declarations of interest, Roland Franz did not participate in the development and adoption of this scientific output.

Suggested citation: EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), Silano V, Bolognesi C, Castle L, Cravedi J-P, Engel K-H, Fowler P, Franz R, Grob K, Gürtler R, Husøy T, Kärenlampi S, Mennes W, Penninks A, Smith A, Tavares Poças MF, Tlustos C, Wölfle D, Zorn H, Zugravu C-A, Dudler V, Gontard N, Lampi E, Nerin C, Papaspyrides C, Croera C and Milana MR, 2017. Scientific Opinion on the safety assessment of the process 'Märkische Faser', based on NGR technology, used to recycle post-consumer PET into food contact materials. EFSA Journal 2017;15(7): 4898, 12 pp. https://doi.org/10.2903/j.efsa.2017.4898

ISSN: 1831-4732

Table of contents

1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008[1] of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[2] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States competent Authorities which transmit the applications to the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process Märkische Faser, EU register No RECYC0135. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2016-00139. The dossier was submitted on behalf of Märkische Faser GmbH.

According to Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process Märkische Faser is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET make part of this evaluation.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008). Applications shall be submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

The following information on the recycling process was provided by the applicant and used for the evaluation:

- General information:
  - general description,
  - existing authorisations.
- Specific information:
  - recycling process,
  - characterisation of the input,
  - determination of the decontamination efficiency of the recycling process,
  - characterisation of the recycled plastic,
  - intended application in contact with food,
  - compliance with the relevant provisions on food contact materials and articles,
  - process analysis and evaluation,
  - operating parameters.

---

[1] Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

[2] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

2.2. Methodologies

The principles followed for the evaluation are described here. The risks associated to the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are crucial points for the risk assessment (see guidelines on recycling plastics; EFSA, 2008).

The criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food are described in the scientific opinion developed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel, 2011). The principle of the evaluation is to apply the decontamination efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, conservatively set at 3 mg/kg PET for contaminants resulting from possible misuse. The resulting residual concentration of each surrogate contaminant in recycled PET (C_{res}) is compared with a modelled concentration of the surrogate contaminants in PET (C_{mod}). This C_{mod} is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 μg/kg body weight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible. If the C_{res} is not higher than the C_{mod}, the recycled PET manufactured by such recycling process is not considered of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

3.1. General information

According to the applicant, the recycling process Märkische Faser is intended to recycle food grade PET containers to produce recycled PET pellets using the NGR technology. The recycled pellets are intended to be used to manufacture new food packaging articles, typically films and trays for all kind of foodstuffs. These final materials and articles are intended to be used in direct contact for long term storage at room temperature. Trays made of this PET are not intended to be used for microwave or oven applications.

3.2. Description of the process

3.2.1. General description

The recycling process Märkische Faser produces recycled PET pellets from PET containers, mainly bottles, coming from post-consumer collection systems (kerbside and deposit systems).

The recycling process is composed of the four steps below.

- Step 1: sorting and grinding of post-consumer PET containers, mainly bottles, into flakes follow by an intensive washing and drying of the flakes. This step is performed by third parties.
- Step 2: melting of washed flakes.
- Step 3: decontamination of the melt in a melt-state polycondensation process
- Step 4: extrusion and granulation into pellets

The operating conditions of the process have been provided to EFSA.

Recycled pellets, the final product of the process, are checked against technical requirements on intrinsic viscosity, colour and black spots. Recycled pellets are intended to be converted by other companies into food packaging films used for long term storage at room temperature. Trays made of this PET are not intended to be used in microwave and conventional ovens.

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process Märkische Faser is hot washed and dried flakes obtained from PET containers, mainly bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen hygiene bottles, etc. According to information from the applicant, the amount of this non-food container fraction depends on the re-collection system and is below 5%.

Technical data for the hot washed and dried flakes are provided such as information on maximal residual content of poly(vinyl chloride) (PVC), glue, polyolefins, labels, metals, polyamides and moisture (see Appendix A).

3.3. NGR technology

3.3.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process Märkische Faser uses the NGR technology as described below and for which the general scheme, provided by the applicant, is reported in Figure 1. Step 1 is performed by flake suppliers and is not reported in the scheme. Post-consumer PET containers, mainly bottles, are ground and processed into hot caustic washed and dried flakes.

- In step 2, the washed and dried flakes are melted and degassed in an extruder under vacuum. The melt is filtered and pumped to the top of the reactor of step 3.
- In step 3, the melt is decontaminated during a melt-state polycondensation under high temperature and vacuum. In this reactor the molten polymer is exposed, with a high surface, to the decontamination vacuum.
- In step 4, the melt material is homogenised, extruded under vacuum and subsequently pelletised.

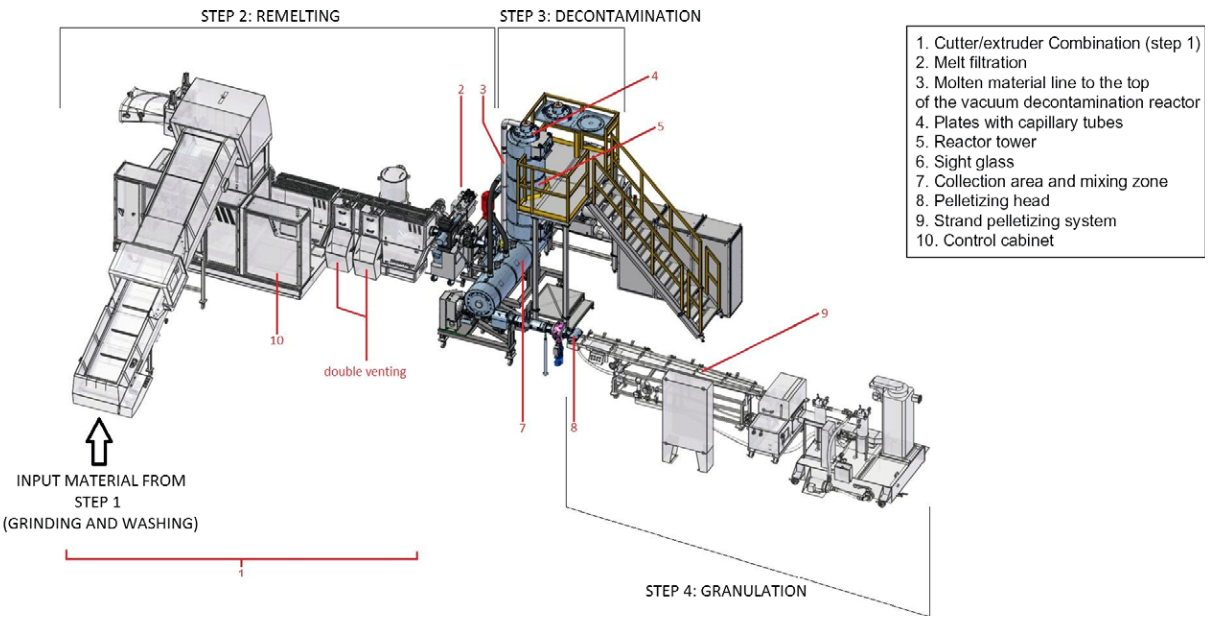


Figure 1: General scheme of the NGR technology

The process is run in a continuous mode under defined operating parameters of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process Märkische Faser, a challenge test on the NGR technology was submitted to the EFSA. According to the applicant, the challenge test was performed at NGR facilities on a pilot plant of reduced capacity.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, phenylcyclohexane, methylsalicylate, benzophenone and methylstearate, selected as surrogate contaminants. The surrogates were chosen in agreement with EFSA guidelines and in accordance with the recommendations of the US Food and Drug Administration. The surrogates include different molecular weights and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

For the preparation of the contaminated flakes, a liquid mixture containing equal amounts of the surrogates was added to 100 kg of PET flakes stored in four barrels. The barrels were sealed and stored for 7 days at 50°C with periodical agitation. After this time, the concentration of surrogates was determined in this material and used as the starting material for the challenge test.

The contaminated flakes were introduced directly on step 2 without a washing step. After melting and decontamination (steps 2 and 3, respectively), at the end of step 4 (extrusion and pelletisation), pellets were collected and analysed for their residual concentrations of the applied surrogates. The decontamination efficiency was then calculated from the concentration difference before and after the process. When surrogates were not detected, the limit of detection was considered for the calculation of the decontamination efficiency. During the challenge test, the temperature of step 3 was increased stepwise and samples were collected at four different temperatures. Although similar results were obtained for each setting, the results of the lower temperature (worst-case situation) were used to calculate the decontamination efficiency and are summarised in Table 1.

Table 1: Efficiency of the decontamination of the NGR technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 4 (mg/kg PET)	Decontamination Efficiency (%)
Toluene	483.7	< 0.1	> 99.98
Chloroform	140.3	< 0.2	> 99.97
Chlorobenzene	790.3	< 0.1	> 99.98
Methyl salicyclate	864.2	< 0.1	> 99.99
Phenylcyclohexane	687.3	0.3	99.96
Benzophenone	718.2	2.4	99.67
Methyl stearate	840.7	1.3	99.85

PET: poly(ethylene terephthalate).

As shown above in Table 1, the decontamination efficiency ranged from 99.67% for benzophenone up to more than 99.99% for methyl salicylate.

Since the challenge test was performed with only contaminated flakes, cross-contamination[3] phenomena can be excluded. Contrary to the recommendations of the EFSA guidelines (EFSA, 2008) the contaminated flakes were not rinsed before being introduced in the recycling process. As the contaminated flakes are melted at the beginning of the extrusion process, before the material is subjected to vacuum, it can be estimated that surrogates are homogeneously distributed in the PET material when the decontamination starts. The concentrations measured before step 2 (Table 1) are not overestimated and can be considered as a worst case. Therefore, the Panel concluded that the results from the challenge test could be used to calculate the decontamination efficiency.

3.4. Discussion

Considering the high temperatures used during the process, the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

Technical data such as information on residual content of PVC, glue, polyolefins, labels, metals, polyamides and moisture are provided for the input materials [washed and dried flakes (step 1)], for the submitted recycling process. The input materials are produced from PET containers, mainly bottles, previously used for food packaging collected through post-consumer collection systems. However, a small fraction of the input may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen hygiene bottles, etc. According to the applicant, the amount of this non-food container fraction depends on the collection system and the process is managed is such a way that in the input stream of the recycling process this amount will be lower than 5%, as recommended by the EFSA CEF

[3] 'Cross-contamination', as meant in the 'Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food', is the transfer of surrogate contaminants from the initially contaminated to the initially not contaminated material (EFSA CEF Panel, 2011).

Panel in its 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is well described. The production of hot caustic washed and dried flakes from collected containers, mainly bottles (step 1) is conducted by the flakes suppliers. The recycled PET is intended to be used to manufacture new food packaging articles as films and trays.

The NGR technology used the following steps to recycle the PET flakes into decontaminated PET pellets: extrusion under vacuum of the washed flakes (step 2), decontamination of the material in a vacuum reactor by melt-state polycondensation (step 3) and extrusion and granulation of the material (step 4). The operating parameters of temperature and pressure, for all the steps of the process, as well as the exposed surface area of the melt and its residence time for the step 3 were provided to EFSA.

The challenge test was performed under conditions that fulfil the requirements described in the EFSA Guidelines (EFSA, 2008). It was conducted in a pilot plant to measure the decontamination efficiency. Because the decontamination efficiency was determined for the complete process from step 2 to step 4, it was not possible to quantify the contributions from each step to the final decontamination.

Therefore, the Panel considered that the extrusion under vacuum (step 2), the decontamination of the material in a vacuum reactor by melt-state polycondensation (step 3) and the extrusion and granulation of the material (step 4) are the critical steps for the decontamination efficiency of the process. Consequently, the pressure and the temperature for the steps 2–4 and the exposed surface area of the melt and the residence time, reflected in a combination factor for the decontamination reactor (step 3) should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA. The decontamination efficiencies obtained for each surrogate contaminant from the challenge tests have been used to calculate the residual concentrations of potential unknown contaminants in pellets (C_{res}), according to the evaluation procedure described in the 'Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination efficiency percentage to the Reference Contamination level of 3 mg/kg PET, the C_{res} for the different surrogates in the challenge test are obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the C_{res} value should not be higher than a modelled concentration in PET (C_{mod}) corresponding to a migration, after 1 year at 25°C, which cannot give rise to a dietary exposure exceeding 0.0025 μg/kg bw per day, the exposure threshold below which the risk to human health would be negligible.[4] Because the recycled PET is intended for general use for the manufacturing of articles containing up to 100% recycled PET, the most conservative default scenario for infants has been applied. Therefore, the migration of 0.1 μg/kg into food has been used to calculate C_{mod} (EFSA CEF Panel, 2011). The results of these calculations are shown in Table 2. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiency from challenge test, residual concentration of surrogate contaminants in recycled PET (C_{res}) and calculated concentration of surrogate contaminants in PET (C_{mod}) corresponding to a modelled migration of 0.1 μg/kg food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.98	0.0006	0.09
Chloroform	> 99.97	0.0008	0.10
Chlorobenzene	> 99.98	0.0006	0.09
Methyl salicylate	> 99.99	0.0003	0.13
Phenylcyclohexane	99.96	0.0013	0.14
Benzophenone	99.67	0.01	0.16
Methyl stearate	99.85	0.0046	0.32

PET: poly(ethylene terephthalate).

[4] 0.0025 μg/kg bw per day is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible (EFSA CEF Panel, 2011).

The residual concentrations of all surrogates in PET after decontamination (C_{res}) are lower than the corresponding modelled concentrations in PET (C_{mod}). Therefore, the Panel considered that the recycling process under evaluation using the NGR technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1 μg/kg food at which the risk to human health would be negligible.

4. Conclusions

The Panel considered that the process Märkische Faser is well characterised and the main steps used to recycle the PET flakes into decontaminated PET pellets have been identified. Having examined the challenge test provided, the Panel concluded that the steps 2, 3 and 4 are the critical steps for the decontamination efficiency of the process. The operating parameters to control their performance are the temperature and pressure for steps 2 and 4, and temperature, pressure, exposed surface area of the melt and residence time for step 3. Therefore, the Panel considered that the recycling process Märkische Faser is able to reduce any foreseeable accidental contamination of the post-consumer food contact PET to a concentration that does not give rise to concern for a risk to human health if:

1) it is operated under conditions that are at least as severe as those obtained from the challenge tests used to measure the decontamination efficiency of the process;
2) the input of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials containing no more than 5% of PET from non-food consumer applications.

Therefore, the recycled PET obtained from the process Märkische Faser intended to be used up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, is not considered of safety concern. Trays made of this recycled PET are not intended to be used, and should not be used in microwave and conventional ovens.

5. Recommendations

The Panel recommended periodic verification that the input to be recycled originates from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5%. This adheres to good manufacturing practice and Regulation (EC) No 282/2008, Art. 4b. Critical steps in recycling should be monitored and kept under control. In addition, supporting documentation should be available on how it is ensured that the critical steps are operated under conditions at least as severe as those in the challenge test used to measure the decontamination efficiency of the process.

Documentation provided to EFSA

1) Dossier "Märkische Faser". May 2016. Submitted on behalf of Märkische Faser GmbH, Germany.
2) Additional data for Dossier "Märkische Faser". November 2016. Submitted on behalf of Märkische Faser GmbH, Germany.
3) Additional data for Dossier "Märkische Faser". February 2017. Submitted on behalf of Märkische Faser GmbH, Germany.

References

EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. EFSA Journal 2008,6(7):717, 12 pp. https://doi.org/10.2903/j.efsa.2008.717

EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part 2: General principles. EFSA Journal 2009;7(5): 1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011. Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2011;9(7):2184, 25 pp. https://doi.org/10.2903/j.efsa.2011.2184

Abbreviations

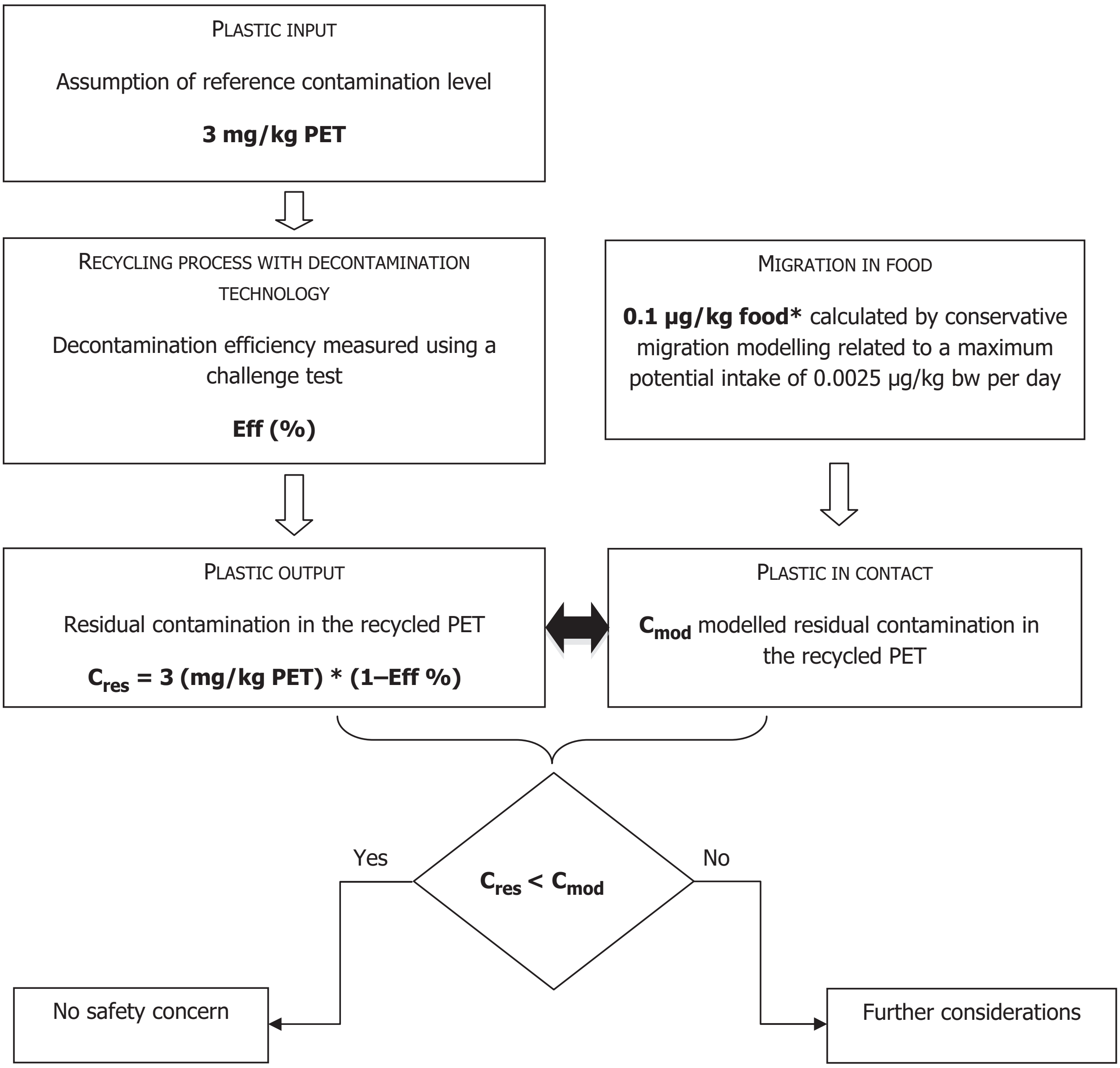
bw	body weight
CEF	Panel Food Contact Materials, Enzymes, Flavourings and Processing Aids Panel
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)

Appendix A – Technical data of the washed flakes as provided by the applicant

Parameter	Value
Moisture max.	1%
Labels max.	50 ppm
PVC max.	10 ppm
Glue max. (inclusive flakes)	50 ppm
Polyolefins max.	100 ppm
Metal max.	80 ppm
Polyamide max.	20 ppm

PVC: poly(vinyl chloride).

Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)



*Default scenario (infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food, respectively.